

Real-world evidence: what is it and can it be trusted?

Philip Wiffen 

There is a new term slipping into submissions—‘real world’ sometimes expressed as ‘real-world data’ (RWD) or ‘real-world evidence’ (RWE). Since the start of 2020, we have published some 10 articles that use this term in some form, six of them from Spain. But what does the term mean?

In that famous children’s book ‘Alice’s Adventures in Wonderland’,¹ there is a now famous quotation from Humpty Dumpty: “When I use a word,” Humpty Dumpty said in rather a scornful tone, “it means just what I choose it to mean—neither more nor less.” “The question is,” said Alice, “whether you can make words mean so many different things.”

In the early days of evidence-based medicine (EBM), there were those who thought that using the term evidence was sufficient without paying attention to the philosophy that lay behind the concept. We need to be sure that the same thing does not happen with the term ‘real world’ and so we need to carefully define what we mean.

The early EBM developments led to advances in critical appraisal as a means to assess evidence and a number of tools are now available for different study designs²; however, I am not aware of such a tool to appraise RWD studies.

There is an emerging literature on the topic of RWD. Lipworth³ from Sydney Australia defines RWD as ‘data collected outside of the laboratory or conventional

randomised controlled trials’. She goes on to list what this might look like including:

- ▶ Public health data such as disease surveillance and population health.
- ▶ Clinical research including data sources for trials that aim to capture the effects of interventions in populations receiving routine healthcare or to generate observational data about the safety and effectiveness of healthcare interventions.

Furthermore, the use of RWD is used to generate RWE which is used to guide regulation, financing or clinical use as well as for broader health service design.²

Gokhale and colleagues⁴ suggest that RWE is ‘a concept that offers an understanding of the effects of healthcare interventions using routine clinical data’. They helpfully point out that while such an approach is attractive, it also opens the doors to biases in both the design and analytical phases of non-experimental studies. The paper written from the point of view of RWE based on diabetes studies is recommended to any who wish to use RWD. It works through a series of issues that are similar to a critical appraisal tool. This paper could provide a useful background as it covers such issues as the types of data sources and study design, and lists the potential biases.

Lipworth³ further points out that those using RWD can be driven by commercial, political, professional or personal self-interest.

I am pleased to publish a commissioned paper in this issue from an experienced team based in Chengdu, West China, titled: ‘Toward the better understanding about real-world evidence: a short

overview of methodologies’.⁵ I have had the privilege of working with one of the authors, Xin Sun, over a good number of years. The paper covers key issues such as sources of data, formulating the research question, developing the dataset as well as appropriate analysis and reporting.

The topic of RWE will be on the agenda for the *EJHP* editors meeting in March 2021 and I am hoping to stimulate discussion among authors and readers to ensure that RWE papers that are published in *EJHP* meet agreed standards as well as provide answers to clinical questions.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Commissioned; internally peer reviewed.

© European Association of Hospital Pharmacists 2022. No commercial re-use. See rights and permissions. Published by BMJ.



To cite Wiffen P. *Eur J Hosp Pharm* 2022;**29**:1. Published Online First 2 December 2021



▶ <http://dx.doi.org/10.1136/ejhp-2021-003081>

Eur J Hosp Pharm 2022;**29**:1. doi:10.1136/ejhp-2021-003163

ORCID iD

Philip Wiffen <http://orcid.org/0000-0001-6085-1307>

REFERENCES

- 1 Carroll L. Alice’s adventures in Wonderland, 1865. Available: <https://www.britannica.com/topic/Alices-Adventures-in-Wonderland>
- 2 Casp checklist. Available: <https://casp-uk.net/casp-tools-checklists/> [Accessed Nov 2021].
- 3 Lipworth W. Real-world Data to Generate Evidence About Healthcare Interventions. *Asian Bioeth Rev* 2019;11:289–98.
- 4 Gokhale M, Stürmer T, Buse JB. Real-world evidence: the devil is in the detail. *Diabetologia* 2020;63:1694–705.
- 5 Liu M, Qi Y, Wnag W, et al. Toward a better understanding about real-world evidence. *Eur J Hosp Pharm* 2022;29:8–11.

Pain Research Unit, Churchill Hospital, Oxford, UK

Correspondence to Professor Philip Wiffen, Pain Research Unit, Churchill Hospital, Thame OX9 3GG, UK; pwiffen@oxfordsrs.org.uk